

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC) and the
Drug Safety and Risk Management Advisory Committee (DSaRM)

AGENDA

May 2, 2011

The committees will discuss safety considerations of ultrasound contrast agents (materials intended to improve the clarity of ultrasound imaging), particularly related to new information and developments since the prior Advisory Committee meeting on the same topic on June 24, 2008. The discussion will include the results of required postmarketing safety studies and data from postmarketing surveillance. Specific drugs to be discussed include: (1) New drug application (NDA) 21-064, perflutren lipid microsphere injectable suspension, Lantheus Medical Imaging, Inc.; (2) NDA 20-899, perflutren protein-type A microspheres injectable suspension, GE Healthcare; and (3) the investigational new drug (IND) application for sulfur hexafluoride microbubble injection, Bracco Diagnostics, Inc. Perflutren lipid microsphere injectable suspension and perflutren protein-type A microspheres injectable suspension are indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border (improve the clarity of imaging of specific areas of the left lower side of the heart).

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| 8:00 a.m. | Call to Order Introduction of Committee | Milton Packer, M.D. Acting Chair, CRDAC |
| | Conflict of Interest Statement | Nicole Vesely, Pharm.D. Designated Federal Officer, CRDAC |
| 8:10 a.m. | <u>FDA Presentation</u> Regulatory History of Ultrasound Contrast Agents | Ira Krefting, M.D. Deputy Director for Safety, Division of Medical Imaging Products, Office of Drug Evaluation IV, CDER |
| 8:30 a.m. | <u>Speaker Presentation</u> Current Cardiological Applications of Contrast Echocardiography | Sanjiv Kaul, M.D. (Guest Speaker) Professor of Medicine and Radiology Head, Division of Cardiovascular Medicine Oregon Health & Science University |
| 9:00 a.m. | <u>Industry Presentation</u> DEFINITY® Post Marketing Studies Results | <u>Lantheus Medical Imaging, Inc.- perflutren lipid microsphere injectable suspension (Definity)</u> Mark Hibberd, M.D. Senior Medical Director, Medical Affairs Lantheus Medical Imaging, Inc. |
| | DEFINITY® Pharmacovigilance Safety Data Review | Dana Washburn, M.D. Vice President, Clinical Development & Medical Affairs Lantheus Medical Imaging, Inc. |
| | DEFINITY® Risk/Benefit Profile | Michael Main, M.D. Cardiologist St. Luke's Mid-America Heart Institute Kansas City, MO |
| 9:30 a.m. | <i>Break</i> | |
| 9:35 a.m. | <u>Industry Presentation</u> | <u>GE Healthcare - perflutren protein-type A microspheres injectable suspension (Optison)</u> |

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AGENDA (continued)

May 2, 2011

Introduction and Optison
Post-Marketing Safety Data

Paul Sherwin, M.D., Ph.D.
Senior Medical Director
Global Clinical Development
GE Healthcare

Post-Marketing Clinical Studies
of Optison Safety

Jonathan Goldman, M.D., FACC, FASE
Executive Vice President-ICON Clinical Research
San Francisco, California
Assistant Clinical Professor of Medicine, UCSF
San Francisco, California

Peer-Reviewed Literature on Optison
Human Safety

Steven Feinstein, M.D., FACC, FESC
Professor of Medicine
Director-Echocardiography Lab
Rush University Medical Center
Chicago, Illinois

Impact of Product Labeling on
Patient Care

Steven Feinstein, M.D., FACC, FESC

Conclusions

Paul Sherwin, M.D., Ph.D.

10:05 a.m.

Break

10:20 a.m.

Industry Presentation

Safety Profile of SonoVue®
(Sulfur Hexafluoride Microbubbles)

**Bracco Diagnostics, Inc - sulfur hexafluoride
microbubble injection (SonoVue)**

Alberto Spinazzi, M.D.
Senior Vice President,
Group Medical and Regulatory Affairs,
Bracco Diagnostics, Inc.

10:50 a.m.

Questions to Industry Presenters

11:10 a.m.

FDA Presentation

Retrospective Observational Cohort
Studies for Definity and Optison

Janelle Charles, Ph.D

Mathematical Statistician, Division of Biometrics VII,
Office of Biostatistics, CDER

FDA Presentation (cont.)

Postmarketing Studies and Surveillance
of Ultrasound Contrast Agents

Ross Filice, M.D.

Medical Officer, Division of Medical Imaging Products,
Office of Drug Evaluation IV, CDER

11:50 a.m.

Questions to FDA Presenters

12:10 p.m.

Lunch

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AGENDA (continued)

May 2, 2011

- 1:10 p.m. Open Public Hearing
- 2:10 p.m. Questions to the Committees
- 3:00 pm. *Break*
- 3:15 p.m. Questions to the Committees (continued)
- 4:00 p.m. *Adjourn*